

CLAIMS

1. An endoscopic device for the partial fundoplication, comprising:
  - a distal bending portion and a flexible portion suitable to be positioned in extended shape within the esophagus of a subject;
  - a positioning assembly comprising two separate elements, one of which is located on said distal bending portion, and the other on said flexible portion;
  - a stapling assembly comprising a staple ejecting device, wherein said staple ejecting device is located on either said bending portion or on said flexible portion, said staple ejecting devices being in working positioned relationship when said two separate elements of said positioning assembly are aligned; and
  - circuitry for determining when said two separate elements of said positioning assembly are aligned.
2. A device according to claim 1, wherein the stapling assembly further comprises an anvil, wherein one of said anvil and of said staple ejecting device is located on said bending portion, and the other is located on said flexible portion, said anvil and said staple ejecting devices being in working positioned relationship when said two separate elements of said positioning assembly are aligned.

3. A device according to claim 1, comprising safety means for disabling the operation of the staple-ejecting device when the two separate elements of the positioning assembly are not aligned.
4. A device according to claim 1, comprising viewing means.
5. A device according to claim 4, wherein the viewing means comprise a video camera.
6. A device according to claim 4, wherein the viewing means comprise illumination apparatus.
7. A device according to claim 1, comprising conventional endoscopic devices and accessories.
8. A device according to claim 7, wherein the conventional endoscopic devices and accessories comprise water and/or air supply and/or suction.
9. A device according to claim 1, further comprising a positioning assembly to position a portion of a stapling assembly within the esophagus at a location of about 5-6 cm above the gastroesophageal junction, when the endoscopic device is in working position.

10. Apparatus according to claim 9, wherein the portion of the stapling assembly comprises an anvil.

11. Apparatus according to claim 9, wherein the portion of the stapling assembly is displaced along the axis of the endoscopic device by the action of a flexible threaded cable coupled with a female thread located in said portion of stapling assembly.

12. Apparatus according to claim 11, wherein the flexible threaded cable is located within the endoscopic device, and is in contact with the female thread through a slit provided in the wall of the body of the endoscopic device.

13. Apparatus according to claim 11, wherein the flexible threaded cable is embedded in the external wall of the endoscopic device, and is in direct contact with the female thread of the portion of the stapling assembly.

14. Apparatus according to claim 11, wherein the flexible threaded cable is rotated using a micrometric assembly, thereby to displace the portion of the stapling assembly positioned within the esophagus by a controlled distance.

15. Apparatus according to claim 10, wherein the anvil is essentially ring-like in shape.

16. Apparatus according to claim 1, wherein the distal portion of the positioning assembly is located on the distal tip.
17. Apparatus according to claim 1, wherein the distal portion of the positioning assembly is located on the outer wall of the distal tip.
18. Apparatus according to claim 1, wherein the distal portion of the stapling assembly is located on the distal tip.
19. Apparatus according to claim 1, wherein the distal portion of the stapling assembly is located on the outer wall of the distal tip.
20. A method for carrying out an endoscopic partial fundoplication of the fundus of the stomach of a patient, comprising the steps of:
  - (a)providing an endoscopic device comprising a bending portion and a flexible portion, a positioning assembly comprising two separate elements, and a stapling assembly comprising a staple ejecting device;
  - (b)moving the distal tip of said endoscopic device so as to engage the fundus of the patient and to displace it toward the lower part of the esophagus;
  - (c) bringing said stapling assembly into working positioned relationship by aligning said two separate elements of said

positioning assembly located one on the bending portion and the other on the flexible portion of said endoscope;

- (d) determining when said two separate elements of said positioning assembly are aligned by maximizing a signal resulting by bringing them into close positioned relationship and received at a signal receiving and analyzing circuit cooperating with said positioning assembly;
- (e) ejecting a plurality of staples from said staple-ejecting device, thereby to connect the tissue between them; and
- (f) rotating the endoscopic device relative to the axis of the esophagus and repeating steps (c) through (e) for as many times as needed to achieve the desired partial fundoplication.

21. A method according to claim 20, wherein the stapling assembly further comprises an anvil, wherein one of said anvil and of said staple ejecting device is located on said bending portion, and the other is located on said flexible portion.

22. A method according to claim 20, wherein the signal resulting by bringing the two separate elements into close positioned relationship is maximized by measuring a physical parameter which is a function of the distance.

23. A method according to claim 20, wherein the signal resulting by bringing the two separate elements into close positioned relationship is maximized by correlating it to a measured physical parameter.

24. A method according to claim 21, wherein the distance between the staples ejecting device and the anvil is between about 0.5 and 1.5 cm.

25. A method for positioning the endoscopic device of claim 1 in pre-aligned working position, comprising the steps of:

- (a) introducing the endoscopic device through the mouth of a patient and locating the position of the gastroesophageal junction;
- (b) determining the distance from a reference point located on the endoscopic device, and the gastroesophageal junction;
- (c) introducing the endoscopic device into the stomach by a length below the gastroesophageal junction sufficient to permit the distal tip to be flexed into a position where the fundus is pushed toward the esophagus;
- (d) locking the endoscopic device such that it cannot move relatively to the axis of the esophagus;
- (e) determining the position of the portion of the stapling assembly positioned within the esophagus using its original axial location,

the distance determined in step b) above, and the radius of curvature of the distal portion of the endoscopic device; and

(f) displacing said portion of the stapling assembly so as to position it in the range of about 5-6 cm above the gastroesophageal junction.

26. A stapling device for the surgical endoscopic device of claim 1, comprising a staple-firing portion and an anvil portion, wherein one of said staple firing portions and one of said anvil portions are located longitudinally displaced from one another along the longitudinal axis of said endoscopic device, with at least a part of said flexible portion between them.

27. A device according to claim 26, wherein the parts of the stapling device are in correct working relationship when one or more alignment/locking pins that are stored in one of the staple firing portions or one of the anvil portions are extended and engage and lock into receptacles that have been provided on the other of said staple firing portion or of said anvil portion.

28. A device according to claim 27, wherein the alignment/locking pins can be extended and retracted from the portion of the stapling device in which they are stored.

29. A device according to claim 28, wherein a dual rack and single pinion system is employed to provide the motion of the alignment/locking pins.

30. A device according to claim 27, wherein the alignment/locking pins can be locked and released from the receptacles that are provided in the portion of the stapling device.

31. A device according to claim 27, wherein two alignment/locking pins are provided.

32. A device according to claim 27, wherein the alignment/locking pins are stored in the anvil portion.

33. A device according to claim 26, wherein one of the staple firing portions or of the anvil portions is located proximately to the proximal end of the flexible portion and the other of said staple firing portions or of said anvil portions is located proximately to the distal end of said flexible portion.

34. A device according to claim 33, wherein the staple firing portion is located proximately to the proximal end of the flexible portion and the anvil portion is located on the distal tip of said flexible portion.

35. A device according to claim 26, wherein one of the staple firing portions or of the anvil portions is located on the flexible portion of the

endoscope and the other of said staple firing portions or of said anvil portions is located proximately to the distal end of said flexible portion.

36. A device according to claim 26, wherein one of the staple firing portions and one of the anvil portions are located on the flexible portion.

37. A device according to claim 26, wherein the flexible portion is an articulation section.

38. A device according to claim 37, wherein the articulation section is a two-way articulation section.

39. A device according to claim 37, wherein the articulation section is a four-way articulation section.

40. A device according to claim 37, wherein activation of the articulation section causes the parts of the stapling device to be brought into correct working relationship.

41. A device according to claim 26, wherein the staple firing portion contains a staple cartridge containing one or a plurality of arrays of staples each array consisting of one or a plurality of staples.

42. A device according to claim 41, wherein the arrays of staples are fired by staple pushers actuated by cams actuatable by proximal means.

43. A device according to claim 41, wherein the staple cartridge is indexable after the firing of each of the arrays of staples by the action of a proximal actuating device.

44. A device according to claim 41, wherein the number of the arrays of staples is three and the number of staples in each of said arrays is five.

45. A device according to claim 41, wherein the staples of each array are arranged in three rows with the pinholes aligned with the middle row.

46. A device according to claim 26, comprising safety means for disabling the operation of the staple firing portion when the two separate elements of the stapling device are not aligned.

47. A device according to claim 27, wherein the alignment/locking pins are manufactured such that the pin tips can be broken by the force exerted by unbending the articulation section.

48. An endoscope according to claim 1, comprising two or more separate optical channels that produce two or more distinct views, each of said optical channels consisting of an objective lens and a means of capturing or

viewing the image; each channel optionally also including one or more of the following elements: a) an optical relay system; b) an ocular; and c) a coupling lens suitable to deliver the image acquired by said objective lens to an image sensor and display apparatus; wherein each objective lens is located at a different position along the length of the endoscope.

49. An endoscope according to claim 48, in which each of said distinct multiple views may be formed by a single optical channel to produce a monocular view, or by multiple optical channels to produce a binocular or stereoscopic view.

50. An endoscope according to claim 48, in which the components of said optical channels and said display apparatus are chosen such that said endoscope can operate in either the visible, ultraviolet, infrared, or x-ray portions of the electromagnetic spectrum.

51. An endoscope according to claim 48, in which said objective lens, ocular, and coupling lens have either fixed focal length, multiple focal lengths, or variable focal lengths.

52. An endoscope according to claim 48, in which each of said distinct views is at an angle of between 0 and 180 degrees with respect to the mechanical axis of said endoscope.

53. An endoscope according to claim 49, in which the field of view of each of each of said optical channels may be of any suitable shape, including, but not limited to circular and rectangular, and has an angular view of up to 180 degrees or more.

54. A distal tip for the Gerd endoscope of claim 1, comprising:

- a) a socket suitable to receive elements of a stapling device;
- b) at least one illumination channel; and
- c) at least one objective lens coupled to an optical relay system.

55. A distal tip according to claim 54, further comprising a suction and/or irrigation channel.

56. A method for determining the relative position of two parts of an endoscopic device comprising measuring the distance between said parts based on the use of one or more transducers or arrays of transducers functioning as transmitters of ultrasonic signals and one or more transducers or arrays of transducers functioning as receivers of said ultrasonic signals, and determining the degree of alignment therefrom.

57. Endoscopic device comprising a system for measuring the distance between and/or the relative alignment of two objects located at two different locations along the length of said endoscope comprising one or more transducers or arrays of transducers functioning as transmitters of

ultrasonic signals located on, or near, one of said objects and one or more transducers or arrays of transducers functioning as receivers of said ultrasonic signals located on, or near, the other of said objects.

58. Endoscopic device according to claim 57, wherein at least one of the transducers or arrays of transducers functioning as receivers of ultrasonic signals is replaced by a reflector and at least one of the transducers or arrays of transducers functioning as transmitters of said ultrasonic signals also functions as a receiver of said signals.

59. Endoscopic device according to claim 58, wherein a single ultrasonic transducer, used to both transmit and receive the ultrasonic signals, is mounted on, or near, one of the objects and at least one reflector is mounted on, or near, the second object, said reflector being suitable to reflect back a pattern that can be translated into the position and orientation of said objects relative to each other.

60. Endoscopic device according to claim 59, comprising a reflecting device consisting of two, or more, parallel reflecting planar surfaces intersected, at an angle of 90 degrees or less, by one or more planes to form one, or more, step-like configurations.

61. Endoscopic device according to claim 60, wherein some or all of the steps in the step reflector have different depths.

62. A method according to claim 56, wherein an anvil unit of a stapler system is one of the objects to be aligned and a stapler deployment unit containing a stapler cartridge is the other object.

63. A stapler cartridge for an endoscopic device of claim 1, wherein one or more reflectors of ultrasonic waves is created on or within or as an integral part of the surface of said cartridge.

64. A stapler anvil unit or a stapler cartridge for an endoscopic device of claim 1, wherein a transducer that transmits only, or receives only, or both transmits/receives is mounted into said stapler anvil unit or said cartridge unit.